

TECHNOLOGY VERIFICATION OF COMMERCIALY AVAILABLE
TECHNOLOGIES FOR CLEANING BUILDING VENTILATION AIR
CONTAMINATED WITH BIOLOGICAL OR CHEMICAL AGENTS

Quality Management Plan

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List of Acronyms

ADQ	Audit of data quality
ANSI	American National Standards Institute
APPCD	Air Pollution Prevention and Control Division
ASQC	American Society for Quality Control (currently known as ASQ, American Society for Quality)
CAT	Center for Aerosol Technology
CEM	Center for Environmental Measurements
DQA	Data quality assessment
DQI	Data quality indicator
DQO	Data quality objective
EISD	Environmental and Industrial Sciences Division
ETU	Engineering and Technology Unit
EPA	Environmental Protection Agency
ESE	Environmental Sciences and Engineering
ETV	Environmental Technology Verification
GVP	generic verification protocol
ISO	International Organization for Standardization
NIST	National Institute of Standards and Technology
NRMRL	National Risk Management Research Laboratory
PARCCS	precision, accuracy, representativeness, comparability, completeness, and sensitivity
PE	performance evaluation
PM	project manager
PO	project officer
QA	quality assurance
QAPP	quality assurance project plan
QC	quality control
QM	quality manager (QM at RTI is referred to as QM and at EPA as EPA QM)
QMP	quality management plan
RTI	Research Triangle Institute
SG	Stakeholder Group
SEG	Science and Engineering Group
SOP	standard operating procedure
SRM	Standard Reference Material
TSA	technical systems audit

1.0 INTRODUCTION

This quality management plan (QMP) applies to RTI's program for technology verification of commercially available technologies for cleaning building ventilation air contaminated with biological or chemical agents (the Program) (funded by the U.S. Environmental Protection Agency (EPA) under General Services Administration Contract GS10F0283K-BPA-1. The program is part of EPA Environmental Technology Verification Program (ETV), which was established in 1995 to accelerate the development and commercialization of improved environmental technologies through third-party verification testing and reporting on the tested technologies' performance. The program verifies the environmental performance of commercial-ready technologies. Verification provides potential purchasers and permittees with an independent and credible assessment of what they are buying and permitting. Verification tests use approved protocols. A technology verified performance is reported in verification statements signed by EPA.

The primary objective of the program is to create a highly reputable verification testing program for air cleaning technologies. The quality assurance (QA) activities of this program will help to ensure that the results of the verification tests are credible and technically defensible.

This document and the quality manual for RTI's environmental work, *RTI Quality Management Plan (QMP) for Environmental Programs* (RTI, 2003), are the basis for QA for the program. These documents describe the policies, organizational structure, responsibilities, procedures, and quality systems that will be followed under this contract to meet the requirements of American National Standards Institute/American Society for Quality Control (ANSI/ASQC) Standard E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC, 1994). This document describes the quality systems for this contract and should be considered a program-specific elaboration of RTI's QMP. This document complies with the EPA document, *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a).

The following sections are numbered and named in parallel with the sections in the QMP and in ANSI/ASQC Standard E4-1994.

2.0 PART A: MANAGEMENT SYSTEMS

2.1 MANAGEMENT AND ORGANIZATION

2.1.1 RTI

RTI is an independent organization dedicated to conducting innovative, multidisciplinary research that improves the human condition. With a worldwide staff of more than 2,400 people, RTI is active in health and pharmaceuticals, advanced technology, survey and statistics, education and training, economic and social development, and environmental protection. Universities in North Carolina founded RTI in 1958 as the first scientific organization in and the centerpiece of the Research Triangle Park. Today, RTI serves clients in government, industry, academia, and public service throughout the United States and abroad.

RTI management has established the following quality policy:

RTI will provide to our clients superior quality research, development, and technical services that meet the highest standards of professional performance, satisfy client requirements, and deliver exceptional value. We will achieve this by

- *Working with our clients to define requirements and clarify expectations, including time and cost constraints;*
- *Assuring that our products and services comply with requirements and meet or exceed client expectations;*
- *Striving to continuously improve our products and services;*
- *Recruiting, developing, and retaining highly qualified, motivated staff.*

The Science and Engineering Group (SEG) is one of RTI's technical research groups. It develops basic information, regulatory strategies, and new technologies for environmental protection, defense, semiconductor materials, aerospace systems, chemistry, life sciences, and by conducting research and providing technical services and developing virtual reality systems. SEG employs personnel numbering more than 600 natural and social scientists, engineers, and administrative support personnel. Dr. Satinder Sethi, Senior Vice President for SEG, is responsible for all aspects of SEG's financial and technical performance.

2.1.2 Responsibilities of Team Members

The organization chart for the program is presented in Figure 1. Dr. David Ensor, RTI Fellow and Director of the Center for Aerosol Technology (CAT) is the Program Manager (PM) and manages program activities and coordinates them with the Stakeholder Group (SG). Reporting to the PM are the Deputy PM (i.e., Debbie Franke of CAT), an independent Quality Manager (QM) (i.e., Gene Tatsch of the Environmental and Industrial Sciences Division [EISD]), and test leaders. RTI does not anticipate the use of any subcontractors for this project. The specific responsibilities of the team members are summarized in Tables 1 and 2.

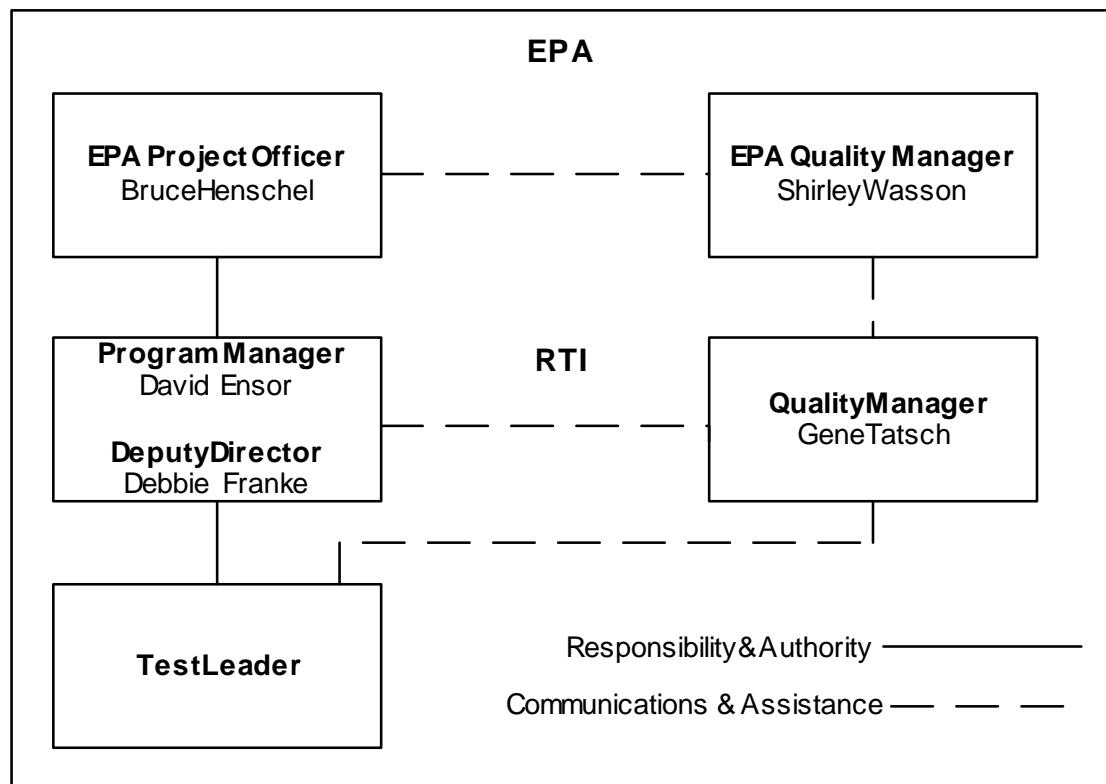


Figure 1 - Organization

The PM has overall responsibility for program activities, which includes oversight for all verification testing and reporting, negotiations with technology developers and vendors, selection of specific technologies for verification testing, management of RTI personnel, and coordination with the SG and the EPA Project Officer (PO). The PM serves as the chair of the SG. The PM has overall responsibility for quality at the program level and in verification tests. The PM may delegate specific technical activities to RTI personnel, but he retains responsibility for the quality of any delegated technical activities. The PM manages the preparation of generic verification protocols (GVPs) and reviews and approves test/QA plans, verification reports, and verification statements. The PM submits these documents to the EPA PO for EPA review and approval.

With the advice and concurrence of the EPA PO, the PM chairs and coordinates the SG to guide and direct activities, to assist in selecting and prioritizing technologies for verification testing, and to serve as a communications link with their constituents. The SG is made up of 15 to 20 leaders from various segments of the air cleaning community, including government (Department of Defense, State Department, General Services Administration, and Federal Trade Commission), trade associations representing technology developers/vendors, professional associations, and EPA representatives, including the PO. The EPA PO is consulted concerning PM's selection of SG members. The SG members have broad experience in the homeland security and air cleaning fields. They provide the verification center with a diversity of opinions and viewpoints concerning air cleaning technologies and their application.

Table 1. Program-Level Responsibilities

Program-Level Responsibilities	PM *	Deputy PM	QM	SG
Overall program and quality responsibility	X			
Substitute for PM when absent		X		
Perform PM's functions as delegated		X		
Coordinate activities with EPA	X			
Communicate activities to SG and constituents	X			
Assist in communicating activities to constituents				X
Prepare QMP; revise as needed			X	
Review and approve program-level documents	X			
Implement quality system (as per QMP)	X			
Communicate with EPA QM			X	
Oversee quality activities			X	
Assess quality system on an annual basis			X	
Submit program-level quality documents to EPA	X			
Chair and coordinate SG meetings	X			
Review activities & advise PM				X
Select and prioritize technologies	X			
Assist in selecting and prioritizing technologies				X
Provide advice about specific technologies				X
Review and approve test-level quality documents	X		X	
Oversee verification tests	X			
Review and approve verification reports and statements	X		X	
Submit test-level quality documents, VR, and VS to EPA	X			
Store program-level documents and records	X			

* The PM may delegate program-level technical activities for specific technology areas to RTI personnel, but he retains the responsibility for the quality of any delegated technical activities

The Deputy PM reports to the PM and substitutes for the PM if that individual is absent. The Deputy PM is responsible for any functions delegated by the PM.

The QM is responsible for the preparation and revision of this QMP. The QM assists the PM in the preparation of GVPs. The QM communicates directly with the EPA QM on quality-related issues. The QM reviews and approves test/QA plans, verification reports, verification statements, verification test results, and associated quality records. The QM is free from personal and external barriers to independence, is organizationally independent from data collection activities, and is able to maintain an independent attitude and appearance. The QM is also responsible for conducting independent technical assessments (i.e., technical systems audits [TSAs] and performance evaluations [PEs]) of verification tests in cooperation with the EPA

QM. The QM is responsible for determining the effectiveness of corrective actions implemented in response to independent assessment findings. The QM will review this QMP as needed and will revise this document as necessary to reflect any changes that have occurred in the organization and the policy of the program or in EPA quality requirements since the last revision. These responsibilities are described in greater detail in Section 2.1.4.

Table 2. Test-Level Responsibilities

Responsibility	PM	QM	Test Leader
Maintain internal communications	X	X	X
Develop and manage verification test budget			X
Report progress and costs to PM			X
Identify technologies and vendors of technology			X
Select specific technologies for testing	X		
Prepare test/QA plan			X
Assist in development of test/QA plan		X	
Review and approve test-level quality documents	X	X	
Submit test-level quality documents to EPA	X		
Oversee testing-organization activities		X	
Oversee QA aspects of verification tests		X	
Select and manage test staff			X
Conduct verification test			X
Provide test-level quality training		X	
Implement test-level quality training			X
Conduct technical assessments of tests		X	
Conduct audit of data quality (ADQ) of test data		X	
Develop and implement corrective actions			X
Determine effectiveness of corrective actions		X	
Prepare verification report and statement (VR,VS)			X
Review quality aspects of VR and VS		X	
Review and approve test results, VS, and VR	X	X	
Submit VS and VR to EPA	X		
Store test-level quality documents & test data			X

* The PM may delegate test-level technical activities in a specific technology area to RTI personnel, but he retains responsibility for the quality of any delegated technical activities.

2.1.3 Quality Management

Overall responsibility for quality at the program level and in all verification tests remains with the PM. The PM has resources available to ensure conformance with EPA quality requirements. The PM has the authority to issue a stop work order in the event that unsafe work or work of inadequate quality is identified. The PM reviews and approves GVPs, test/QA plans, verification reports, and verification statements.

The independence and objectivity of the program quality system is bolstered by the QM being located in a different EG administrative unit (i.e., EISD) from RTI's testing personnel (i.e., CAT). The QM's only organizational connection to the program is to the PM. Reports of quality document reviews, reviews of verification test results, and assessment findings go directly from the QM to the PM. These individuals are free of any real or perceived conflicts of interest as might occur from too close of an administrative association with the data collection activities. They have no stake in the outcome of the verification tests other than that the environmental data be collected objectively and in accordance with the quality documents and EPA quality requirements.

The QM is responsible for reporting to the PM whether verification tests are performed in compliance with EPA quality requirements and with the quality requirements in this document, in GVPs, and in test/QA plans, and whether test results demonstrate that test data attain DQOs. Following are the specific responsibilities of the QM:

- Preparing this document, reviewing it on an annual basis, and revising it as needed;
- Assisting test leaders regarding quality issues relating to specific verification tests;
- Reviewing and approving the GVPs, test/QA plans, and any needed SOPs that are developed by test leaders;
- Communicating with the PM, test leaders, and the EPA QM regarding quality-related issues;
- Conducting self-assessments of the program quality system and test-specific technical assessments of verification tests in cooperation with the EPA QM;
- Determining the effectiveness of corrective actions implemented in response to independent assessment findings.
- Reviewing and approving the test results and the QA and quality control (QC) data from verification tests to determine whether test data attain DQOs; and
- Reviewing and approving verification test reports and verification statements.
- Performing an ADQ for at least 10 percent of verification test data;
- Reviewing and approving the test results and the QA and QC data from verification tests to determine whether test data attain DQOs; and
- Assisting the test leader in the preparation of the quality-related content of each verification report and verification statement.

2.2 QUALITY SYSTEM AND DESCRIPTION

The quality system for the program has five levels. The foundation level consists of *RTI Quality Management Plan (QMP) for Environmental Programs*, which is an umbrella document that provides a "road map" of how quality for environmental programs is managed at RTI. Quality systems at RTI operate at the level of research units, divisions, centers, programs, and labs, rather than one quality system operating uniformly across the entire organization. The RTI QMP provides guidance for the RTI-wide approach to quality, but does not have direct authority over this program because *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a) is based on the ANSI/ASQC Standard E4-1994, which is a two-party agreement system. What matters legally is the program QMP (this document), which has been

developed to comply with the EPA ETV QMP. The RTI QMP provides standardized language and a coherent framework for improving the consistency among QMPs for environmental programs throughout RTI. When coupled with additional tools, such as project QMP templates, examples, and model SOPs, this document provides guidance for RTI projects that prepare environmental QMPs and reduces the effort required to write them.

The second level consists of this document, which describes the program quality system. It is a program-specific elaboration of the RTI QMP and the EPA ETV QMP.

The third level consists of the test-specific test/QA plan, which is prepared by the test leader, in cooperation with the QM. It is reviewed by the PM and QM and is submitted to the EPA PO for approval. All data must be generated in accordance with the test/QA plan. There may also be GVPs, but they are not required. These documents are reviewed by the SG and are submitted to the EPA PO for approval. These documents define the types and characteristics of data that must be present in verification statements and reports in order for technology-specific verification tests to be accepted as credible by EPA and other stakeholders.

The test/QA plan must meet all the requirements for QA project plans, which are specified in *EPA Requirements for Quality Assurance Project Plans. EPA QA/R-5 (EPA, 2001b)*. It contains all the required elements of a QAPP. Additional information regarding QA project plans can be found in *EPA Guidance for Quality Assurance Project Plans. EPA QA/G-5 (EPA, 2002)*.

The test/QA plan must contain a detailed description of the planned verification test, including the organizational structure, its management and personnel, the test schedule, test documentation, sampling and analytical methods, and other operational procedures. It also must specify the QA and QC procedures, calibration traceability, and DQIs for obtaining verification data of sufficient quantity and quality to satisfy the DQOs as specified in the document. The test/QA plan must describe how verification test data will be reconciled with the DQOs. Test/QA plans are described in more detail in Section 3.1.2.

Operation-specific SOPs provide detail for specific repetitive activities relevant to this project (see section 3.1.3)

The final level consists of the assessments of the quality system and technical assessments (e.g., TSAs, PEs, and ADQs) that will be conducted during the verification tests by the QM in cooperation with the EPA QM. The findings of the quality system and technical assessments will be reported by the QM to the PM. Assessments of the quality system and technical assessments are described in greater detail in Sections 2.9 and 3.4.

2.3 PERSONNEL TRAINING AND QUALIFICATIONS

The PM is responsible for assessing the needs, providing the resources, and monitoring the progress of professional development and general training for RTI-based program personnel. The PM identifies general training needs by evaluating personnel qualifications, experience, and performance based on each position's job description and documented performance expectations as applicable. General training needs are assessed and documented as part of the evaluation of each employee's performance in the verification center. The Deputy PM assists the PM providing active support and advice for the daily operations of the project.

The QM is selected based on the following qualifications:

- Educational background and/or a degree relevant to the application of QA principles to technology demonstration projects and programs,
- Work experience specific to QA of technology demonstration projects and programs, and
- Work experience in quality management and QA.

Assessors have a minimum of four years' full-time appropriate practical workplace experience (not including training), at least two years of which have been in QA activities. They have undergone training to the extent necessary to ensure their competence in the skills required for carrying out assessments and for managing assessments. They are free from personal and external barriers to independence, are organizationally independent from data collection activities, and are able to maintain an independent attitude and appearance.

Test leaders are selected based on the following qualifications:

- Educational background and/or a degree that is directly relevant to the technology,
- Work experience specific to the technology, and
- Work experience in project management.

Test leaders are responsible for assessing personnel qualifications to perform verification tests and for identifying test-specific training needs. They identify test-specific training needs by evaluating personnel qualifications, experience, and performance based on the requirements in the project's scope of work. Particular areas that are evaluated include health and safety training and procedures for handling confidential information, as applicable. Training reassessment is conducted whenever an individual's job function changes, such as reassignment to a new work group, job redesign, reorganization, or promotion. Supplemental training is provided when deficiencies in performance are observed.

Testing personnel are selected by the test leader based on the following qualifications:

- Educational background and/or a degree that is directly relevant to the technology, and
- Work experience specific to the technology.

Testing personnel assigned to a verification test are given only those tasks and responsibilities that are commensurate with their training, education, and work experience. For example, a laboratory analyst is taught unfamiliar sampling or measurement procedures through externally provided training courses or through in-house training. Personnel performing data verification or validation have the appropriate background in science or engineering and appropriate background in the measurements being verified or validated, and they must demonstrate competence at the measurement procedure to an experienced supervisor.

2.4 PROCUREMENT OF ITEMS AND SERVICES

RTI Policy No. 4001, *Institute Procurement*, (<http://staffnet.rti.org/policy/PAP/docs/4001.pdf>) and RTI's *Office of Purchasing Standard Operating Procedures Manual* (http://staffnet.rti.org/services/purchasing/docs/OP_SOP.pdf) should be consulted for a general description of quality systems for procurement of items and services. RTI has obtained International Organization for Standardization (ISO) 9001:2000 registration for its purchasing procedures.

RTI does not expect to use any subcontractors for this project.

2.5 RECORDS

Program quality records are the following documents:

- The program Quality Management Plan (this document),
- The minutes of SG meetings,
- GVPs,
- Test/QA plans and SOPs,
- Raw data (all written and electronic data generated when a verification test is conducted),
- Verification reports and verification statements, and
- Project reviews and assessment reports.

This document is prepared by the QM, reviewed and approved by the PM and the EPA PO. It will be reviewed by the QM on an annual basis and will be updated as necessary. The updated document will be reviewed and approved by the PM and the EPA PO. It will be retained by the program office for a period of not less than 7 years after final payment of the contract in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a). The PM is responsible for establishing procedures to securely store this document.

Minutes from SG meetings are prepared by program staff and are reviewed and approved by meeting attendees and the PM. They will be retained by the program office for a period of not less than 7 years after final payment of the contract. The PM is responsible for establishing procedures to securely store these documents.

Test/QA plans, GVPs and any SOPs that are needed for verification tests will be prepared by the test leaders with the assistance of the QM. They will be reviewed and approved by the PM, the QM, and the EPA PO before their use. The test/QA plans will be retained by the program office for a period of not less than 7 years after final payment of the contract. The test leaders and the QM are responsible for establishing procedures to securely store test/QA plans in their respective organizations. The test leader is responsible for establishing procedures to securely store any SOPs.

Raw data (electronic and printed) collected during verification tests, and any calculations or documents derived from such data will be retained by the program office for a period of not less than 7 years after the final payment of the contract. These data, calculations, and documents will be clearly identified by verification test, date and observer/author. The test leader is responsible for establishing procedures to securely store these data, calculations, and documents.

Verification reports, including three- to five-page verification statements, that thoroughly document the verification test results will be prepared by the test leaders with assistance from the QM. The format for the reports will include a thorough description of the technology that was tested, the test methods used and a justification for their selection, the organizations conducting the test and providing QA oversight, the operating parameters and conditions under which the testing was performed, a statistical analysis of the test results, reconciliation of the test results with the DQOs, a statement regarding independent and self-assessment findings, and any limitations on use of the test data. Any necessary deviations from the GVPs and/or test/QA plans will be explained and documented, raw data will be documented, and QA results will be presented. These reports will be reviewed and approved by the PM and the QM and submitted to the EPA PO for approval. They will be retained by the program office for a period of not less than 7 years after final payment of the contract. The PM is responsible for establishing procedures to securely store these documents.

Reports of self-assessments of testing quality and technical systems will be prepared by the QM and will be sent to the test leader. Reports of AQDs of verification test results will be prepared by QM and will be sent to the test leader and the QM. Reports of independent assessment findings of quality and technical systems will be prepared by the QM and will be sent to the PM. Reports of self-assessments of the program quality system will be prepared by the QM and will be sent to the PM. These reports will be available for review during independent assessments. These reports will be retained by the program office for a period of not less than 7 years after the final payment of the contract. The test leader and the PM are responsible for establishing procedures to securely store these project reviews and assessment reports in their respective organizations.

2.6 COMPUTER SOFTWARE AND HARDWARE

The hardware currently used for sampling and measurement generates data that is downloaded either manually or via labview programs to a desktop computer where spreadsheets are used for storing and analyzing the data. All computer hardware/software configurations used to support

verification tests will be tested prior to use. The results of the testing will be documented. The configurations will be properly maintained and documented subsequent to testing. All applications and configurations will be tested using a test data set or by running a shakedown test of the system to ensure that they are operating according to specifications. The program will maintain, control, and document such configurations including:

- Retaining computer support personnel to correct any hardware or software failure with minimal downtime to the program;
- Tracking upgrades to hardware and revisions to software developed by the program
- Documenting software names, versions, and copyright dates; and
- Completely documenting code with comments structured in modular form.

The program does not expect to use commercial software other than for office operations and does not expect to establish acceptance criteria for such software. Part A, Section 6.1 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a) states "If the verification organization uses only commercial software for office operations (e.g., word processing software, spreadsheet software), it is unlikely that they would need specific procedures for assessing software quality".

Computer accounts containing test data will be password-protected. Electronic data transfers will be protected by encryption or other means to prevent tampering and ensure confidentiality.

2.7 PLANNING

The PM will develop an implementation plan for the program. The purpose of this plan is to describe the technical approach that will be followed to implement the verifications. The plan will be delivered to EPA. Elements of the technical approach include the following:

- Organizational Phase/Management- This element includes management functions, outreach, SG, QMP, GVPs, and technology identification and prioritization.
- Technology Verification- This element includes vendor solicitation, GVP and test/QA plan development, testing and evaluation, QA, verification report, and verification statement.
- Schedule- This element presents the anticipated project schedule.
- Success Measures- This element describes measures that are planned to ensure the success of the program.
- Reports- This element describes the reports that the PM will submit to the EPA PO.
- Verification Statements- This element describes the verification statements that will summarize the verification test results.

The implementation plan will also include sections on program management, SG management, technology verification management, quality management, the program QMP, and verification QA/QC.

2.8 IMPLEMENTATION OF WORK PROCESSES

Verification testing will proceed after the test/QA plan has been approved by the EPA PO. Verification tests will be conducted at RTI. Each verification test will be carried out according to the test/QA plan. The data from the test will be compiled, validated, and reported in a form consistent with the objectives of the test. After the test has been completed and the data have been validated by the staff, the QM will perform an ADQ on the data. See Section 3.3 for more information on the implementation of work processes during verification tests.

2.9 ASSESSMENT AND RESPONSE

The goal of an assessment is accomplished by examining the processes used by an organization to plan, implement, and assess the effectiveness of the QA activities that are described in its quality management plan and that are applied to programs that collect or use environmental data.

The purpose of the assessment is to provide valid feedback to management on the adequacy, implementation, and effectiveness of the quality system. The assessment may also examine human resource issues, such as whether personnel have adequate QA training.

The EPA QM and/or the QM will perform self-assessments and independent assessments of the program quality system. They will also perform self-assessments and independent assessments (i.e., TSAs and/or PEs) of measurement systems during verification tests. The QM will conduct an ADQ for all critical measurements at the end of each verification test.

Assessors will have a minimum of four years' full-time appropriate practical workplace experience (not including training), at least two years of which should have been in quality assurance activities. They will have undergone training to the extent necessary to ensure their competence in the skills required for carrying out assessments and for managing assessments. The assessors assigned to conduct a specific assessment will collectively possess adequate professional proficiency for the tasks required. They will be free from personal and external barriers to independence, will be organizationally independent, and will be able to maintain an independent attitude and appearance. They will use due professional care in conducting the assessment and in preparing related reports.

Assessors will have sufficient authority, organizational freedom, and access to programs, managers, documents, and records to:

- Identify both quality problems and noteworthy practices,
- Propose recommendations for resolving quality problems, and
- Independently confirm implementation and effectiveness of corrective actions.

The reports of assessments of quality or technical systems will contain a statement on the effectiveness of the systems that were assessed. The reports will give all of the details of the assessment necessary to understand the current status of the project and to estimate whether

DQOs and DQI acceptance criteria will be attained. It will include an introduction describing the purpose and scope of the assessment, the technical basis for the assessment, an executive summary (as needed), a detailed account of findings and further observations, a list of the assessors, and a list of the test laboratory managers and personnel. The report will recommend corrective actions, if such are indicated by the findings.

Reports of the ADQs will describe the results of custody tracing, a study of data transfer and intermediate calculations, a review of QA and QC data, a study of project incidents that resulted in lost data, and a review of study statistics. The ADQ reports end with conclusions about the quality of the data from the project and their fitness for their intended use.

As specified in Sections A9.4 and B4.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a) responses by the assesseees to adverse findings and recommendations are required within 10 working days of receiving the assessment report. The lead assessor has the responsibility to correct any errors in fact that are demonstrated by evidence to the contrary. Any disputes encountered as a result of assessments will be presented in writing to the PM, who will resolve the disputes. The test leader will be responsible for developing and implementing any corrective actions. The assessors will followup with appropriate documentation to confirm the implementation and effectiveness of the corrective actions.

If assessors identify a severe problem affecting verification quality, the QM will notify the PM to halt the verification until the problem is addressed. If assessors identify a problem endangering the health and safety of personnel, they have the responsibility to bring the danger to the immediate attention of the PM, the test leader, and the on-site testing personnel.

2.10 QUALITY IMPROVEMENT

The PM is responsible for improving the quality of the program's system and processes used to plan and produce verification test data. He is assisted by the QM and all others on the program team.

Activities will be based on the technical expertise of the program staff and stakeholders, review of the results of verification tests, QA assessment findings and inputs from many other sources. Test/QA plans and SOPs will be reviewed and revised to ensure that the testing environment ensures that specified DQOs are attained.

When problems with the program system and processes, or with technology-specific items, are determined by the Program Manager to be significant, the probable root cause shall be identified, appropriate changes determined, implemented and documented in a timely manner.

3.0 PART B: COLLECTION AND EVALUATION OF ENVIRONMENTAL DATA

This section contains the specifications and guidelines that apply to test-specific environmental activities involving the generation, calculation, analysis, evaluation, and reporting of test data.

3.1 PLANNING AND SCOPING

Test/QA plans, GVPs and any SOPs that are needed will be prepared by the test leader with the assistance of the QM. They will be reviewed and approved by the PM, the QM, the EPA PO and the EPA QM. The test leader will be responsible for monitoring the implementation of the test/QA plans and any needed SOPs. All data collected during a verification test must be generated in accordance with the test/QA plan and SOPs that are prepared for that test. The test/QA plan and SOPs will provide sufficient detail to demonstrate that:

- The verification test's technical objectives are identified and agreed upon,
- The intended measurements and data acquisition methods are consistent with the verification test objectives,
- DQI acceptance criteria that are specified in the test/QA plan and SOPs are consistent with the DQOs,
- The assessment procedures are sufficient for determining if measurement data of the type and quality needed and expected are obtained and if measurement data attain DQOs, and
- Any potential limitations on the use of the data can be identified and documented.

3.1.1 Generic Verification Protocols

GVPs will be developed where needed and may actually be written after verification testing has been completed for a technology, if a more general document than the test/QA plan is needed. This section contains a generic version of GVPs that may not be fully implemented in this program. When written first, GVPs provide the framework for development of the more detailed test/QA plan. The specific content and level of detail given in GVPs may vary between different technologies in response to the testing and quality requirements for each technology.

To start the development of a GVP, the test leader, the QM and other program personnel will review existing test methods that might be applicable and prepare a review of their strengths and weaknesses. They will prepare a draft GVP for discussion purposes, either by synthesizing existing test methods or using their technical judgment. DQOs for critical measurements will be clearly defined in the draft GVP. During the development of the draft GVP, SG members will provide input into the GVP to ensure that their constituents' interests are met. To the extent practical, the GVP will be reviewed by the SG members. The draft GVP will be reviewed by the PM and the QM before it is sent to the EPA PO for approval. The GVP will remain a draft document until completion of the first verification so that appropriate improvements and corrections can be made.

Each GVP will contain elements that are common to all technologies, as well as elements that are specific to the technology being tested. It will ensure that all important information is obtained from the verification test.

In general, the GVP may address the following issues:

- General description of the program,
- Responsibilities of all involved organizations,
- Experimental design,
- Equipment capabilities and descriptions,
- DQOs, QA/QC requirements, and test specifications
- Data collection, handling, and reporting,
- The requirements for other documents,
- Health and safety, and
- References.

The QA/QC requirements section of the GVP typically describes the activities that verify the quality and consistency of the work. The GVP will include DQOs for critical measurements, which are qualitative or quantitative statements that

- Clarify the objectives of the verification test;
- Define the most appropriate type of data and amount of data to collect;
- Determine the most appropriate experimental conditions under which to collect the data; and
- Specify tolerable limits on the uncertainty of all critical measurements, which will be used as the basis for establishing DQI acceptance criteria, such as accuracy, precision, limit of detection, and correct chemical identification. Limits on uncertainty may also be expressed as tolerable limits on decision errors (for testing hypotheses) or as acceptance widths for confidence or probability intervals (for estimating parameters).

The process of developing DQOs may be viewed as a strategic planning effort, based on the scientific method, that is used to prepare for data collection. DQOs apply to all verification tests of a technology. The process is described in *Guidance for the Data Quality Objectives Process. EPA QA/G-4* (EPA, 2000). It provides a systematic procedure for identifying performance variables that must be assessed during the verification tests and the data quality that is needed for a credible measurement of that variable. The DQO process may or may not have a statistical basis as is appropriate for the specific technology to be verified.

The QA/QC requirements section of the GVP typically describes the activities that link the DQOs with specific requirements for DQIs, and permit verification of the quality and consistency of the work and provides data quality descriptors, such as accuracy, precision, representativeness, completeness, comparability, and detection limit, as appropriate. Preparation and use of appropriate QA procedures such as QC samples, blanks, split and spiked samples, and performance evaluation (PE) samples to verify performance of the technology being tested can

be described. Frequency of calibrations and QC checks and the rationale for them can be described. Procedures for reporting QC data and results can be given. Who is responsible for each QA activity, and who has the responsibility for identifying and taking corrective action can be specified. However, if these items vary between tests within a given technology, the more appropriate document in which to describe them may be the test/QA plan.

The GVP may cite documents or procedures that explain, extend, and/or enhance the GVP such as related procedures, the published literature, or methods manuals. The specific location of any reference not readily available from a full citation in the reference section should be given (as in a facility-specific standard operating procedure) or attached to the GVP.

3.1.2 Test/QA Plans

Test/QA plans are specific for one or more very similar verification tests. These plans address all emission and process data that will be gathered in the verification test and include a project description, test laboratory organization and responsibilities, DQI acceptance criteria, site selection and sampling and monitoring procedures, analytical procedures and calibration, data reduction and reporting, QC checks, technical assessments, and calculations. Data quality will be preeminent. All QA requirements must be met, including the requirements for review and approval of the test/QA plan by the PM, the QM, and the EPA PO.

Test/QA plans for the program must be developed in accordance with *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations*, EPA QA/R-5 (EPA, 2001b) and *EPA Guidance for Quality Assurance Project Plans*, EPA QA/G-5 (EPA, 2002a).

The QA staff of EPA's Air Pollution Prevention and Control Division (APPCD) consider verification tests to be QA Category II projects, unless otherwise specified by the EPA PO, and they will evaluate test/QA plans according to the QA requirements that APPCD has established for Category II projects. See *Quality Management Plan for the National Risk Management Research Laboratory (NTMRL)* (EPA, 2002b) for information about these QA requirements.

The test/QA plan will include the following elements, where appropriate for the specific verification test. It must note and explain those elements that are not appropriate for the test:

- Title and approval sheet (Include title of plan;; and names, titles, signatures of appropriate approving officials, and their approval dates);
- Table of contents and distribution list (List sections, figures, tables, references, and appendices. List all the individuals who will receive copies of the approved plan);
- Testing personnel and responsibilities (Identify the individuals participating in the test and discuss their specific roles and responsibilities. Provide a concise organizational chart showing the relationships and the lines of communication among all participants;
- Schedule (The anticipated start and completion dates for the project should be given. In addition, this discussion should include an approximate schedule of important project milestones, such as the start of environmental measurement activities);

- Verification test description and test objectives (State the specific problem to be solved or decision to be made and include sufficient background information to provide a historical and scientific perspective for this particular project);
- Identification of the critical measurements, DQI acceptance criteria for critical measurements, verification test schedule, and milestones (Describe the relationship between DQI acceptance criteria and DQOs. EPA requires the use of a systematic planning process to define DQOs and DQI acceptance criteria);
- Documentation and records management (Describe the process for ensuring that testing personnel have the test/QA plan. Itemize the information and records that must be included in the data report package and specify the desired reporting format for hard copy and electronic forms, when used. Identify any other records and documents applicable to the project, such as assessment reports and verification reports, that will be produced. Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period);
- Experimental design (Describe the experimental design or data collection design for the verification test. Classify all measurements as critical or noncritical);
- Sampling procedures (Describe the procedures for collecting samples and identify the sampling methods and equipment. Describe the process for preparing and decontaminating sampling equipment.);
- Sample handling and chain-of-custody procedures (Describe the requirements and provisions for sample handling and custody. Include examples of sampling documentation);
- Analytical procedures (Identify the analytical methods and equipment required. Where appropriate, the methods can be identified by method number, date, and regulatory or literature citation. List any method performance standards. For non-standard method applications, appropriate method performance study information must be presented or cited. If previous performance studies are not available, they must be developed during the verification testing and included as part of the project results);
- Test-specific procedures for assessing DQI acceptance criteria (Identify required measurement QC checks. State or reference the required control limits for each QC check and corrective action required when control limits are exceeded and how the effectiveness of the corrective action shall be determined and documented. Describe or reference the procedures to be used to calculate each of the QC acceptance criteria.);
- Instrument calibration and frequency (State the frequency of each type of QC check. Identify the certified equipment and/or standards used for calibration. Describe or reference how calibrations will be traceable to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument) ;
- Data acquisition and data management procedures (Identify and describe all data handling equipment and procedures to process, compile, and analyze the data. Describe the data management scheme, tracing the path of the data from their generation to their final use or storage. Describe record-keeping procedures. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data.);

- Self-assessments of quality and technical systems and ADQs (Identify the number, frequency, and type of assessment activities. Describe how and to whom the results of the assessments shall be reported. Define the scope of authority of the auditor, including stop work orders);
- Corrective action procedures in response to technical assessment findings (Discuss how corrective actions will be developed and implemented in response to assessment findings. Include details on how the corrective actions will be verified and documented);
- Test status reports and assessment reports (Identify the frequency and distribution of reports issued to inform management of the status of the test; assessment findings, and other significant quality assurance problems and recommended solutions. Identify the preparer and recipients of the reports and the actions that recipients are expected to take as a result of the reports);
- Data reduction, data review, data validation, and data reporting (State the criteria used to review and validate [i.e., accept, reject or quality] data in an objective and consistent manner. Describe the process to be used for validating and verifying data, including the chain of custody for data. Discuss how issues shall be resolved. Describe how the results are conveyed to the data users.);
- Reporting of DQIs for critical measurements and reconciliation of verification test data with DQOs (Describe how the data will be reconciled with the DQOs. Outline the proposed methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of verification test. Describe how the reconciliation process will be documented); and
- Limitations of the data (Describe how issues will be resolved and discuss how limitations on the use of the data will be reported).

Although the approved test/QA plan must be implemented as prescribed; it is not inflexible. Because of the complex and diverse nature of ETV verification testing, changes to already approved plans are often needed. When such changes occur, the QM will determine if the change significantly impacts the technical and quality objectives of the project. When a change is significant, the test leader with the assistance of the QM will modify the plan to document the change and submit the revision for approval by the EPA PO. The change can be implemented only after the revised plan has been approved.

DQIs are qualitative and quantitative measures of principle quality attributes. They are used in test/QA plans for specifying requirements for the acceptability or utility of measurement data. Historically, DQIs sometimes have been incorrectly equated with DQOs, which are specifications for decision making. DQIs and DQI acceptance criteria are developed to allow it to determine from QC checks during a verification test whether the verification test data will attain the DQOs at the completion of the test.

While DQOs state what the verification test data user's needs are, they do not provide sufficient information about how these needs can be satisfied. The testing staff who will participate in generating the data need to know the DQI acceptance criteria that must be satisfied to attain the DQOs. One of the most important features of the test/QA plan is that it links the DQOs with

DQI acceptance criteria. Although the level of rigor with which this is done and documented will vary widely depending on the technology being tested and the measurement systems that are involved, establishing this linkage in the test/QA plan represents an important advancement in the implementation of the quality system.

The establishment of acceptance criteria for the DQIs sets quantitative goals for the quality of data generated in the verification tests. For the quantitative measurement parameters, the test/QA plan must describe test-specific measurement and calculation procedures for assessing DQIs. Acceptance criteria for DQIs should be consistent with the DQOs, and, where possible, acceptance criteria for quantitative DQIs should be derived from quantitative DQOs.

The six principle DQIs that are related to environmental measurements and sampling are precision, accuracy, representativeness, comparability, completeness, and sensitivity (PARCCS). Secondary DQIs include selectivity, recovery efficiency, memory effects, limits of quantitation, repeatability, and reproducibility.

EPA's Guidance for Data Quality Indicators, EPA QA/G-5i (EPA, 2001c) provides more information about how to prepare DQIs and how to establish them in the context of DQOs.

3.1.3 Standard Operating Procedures

If another level of detail beyond the test/QA plan is needed for describing test activities, SOPs must be written. The SOPs must be prepared and approved before the start of the verification test. They must be available for review by the PM, the QM, and EPA as part of the review and approval process for test/QA plans. They must also be available for review during self-assessments and independent assessments.

An SOP is a set of written instructions that document a routine or repetitive activity. The development and use of SOPs are integral parts of a successful quality system because they provide testing personnel with the information that is needed to perform a job properly, and they facilitate consistency in the quality and integrity of verification test data. SOPs describe both technical and administrative operational elements that would be managed under a test/QA plan. *EPA's Guidance for the Preparation of Standard Operation Procedures (SOPs), EPA QA/G-6* (EPA, 2001c) provides more information about how to prepare SOPs.

The technical SOP needs to include the specific steps aimed at initiating, coordinating and recording and/or reporting the results of the activity, and it should be tailored only to that activity. Cited published methods may not contain pertinent information for conducting the procedure-in-house. The SOP should fit within the framework presented here, but this format can be modified, reduced, or expanded as required. The technical SOP should address three areas as are described below:

1. Procedural Area- This section can include the following items as appropriate for the test:
 - Scope and applicability (describing the purpose of the process or procedure and any organizational or regulatory requirements);
 - Summary of method (briefly summarizing the procedure);
 - Definitions (acronyms, abbreviations, and specialized forms used in the SOP);
 - Health and safety warnings (indicating activities that could result in possible personal injury), including medical assistance and site evacuation plans;
 - Cautions (indicating operations that could result in personal injury or loss of life and explaining what will happen if the procedure is not followed or is followed incorrectly; warnings should also be listed at the critical steps in the procedure);
 - Interferences (describing any component of the process that may interfere with the accuracy of the final product);
 - Personnel qualifications (denoting the minimal experience the SOP follower should have to complete the task satisfactorily) ;
 - Equipment and Supplies (listing and specifying, where necessary, equipment, materials, reagents, chemical standards and biological specimens);
 - Procedure (identifying all pertinent steps, in order, and materials need to accomplish the procedure such as:
 - Instrument or Method Calibration and Standardization
 - Sample Collection
 - Sample Handling and Preservation
 - Sample Preparation and Analysis (such as extraction, digestion, analysis, identification and counting procedures)
 - Troubleshooting
 - Data Acquisition, Calculations & Data Reduction Requirements, such as listing any mathematical steps to be followed
 - Computer Hardware & Software (used to manipulate analytical results and report data)
 - Data and Records Management (e.g., identifying any forms to be used, reports to be written, and data and record storage information).
2. Quality Control and Quality Assurance Area- QC procedures are designed to allow the evaluation of the quality and consistency of the verification test results. Examples of QC procedures include instrument calibrations and QC materials (such as blanks, split and spiked samples, and PE samples) to verify the performance of the technology being tested. Criteria for determining success can be included in the SOP as appropriate. The frequency of required calibrations and QC checks and the rationale for the decision regarding the frequency can be described. Acceptance criteria for DQIs and corrective actions required when these criteria are exceeded can be described.

The SOP can specify and describe any QA procedures that are integral parts of the verification test, including self-assessments and independent assessments (e.g., TSAs, PEs, and ADQs). It can specify who or what organization is responsible for each QA activity and where or how PE samples are to be procured and/or verified.

3. Reference Area- The SOP should fully reference related documents or procedures, such as related SOPs, published literature, and methods manuals. However, such reference citations cannot substitute for the thorough description of the method being followed. All references that are noted in the SOP should be fully cited and references that are not readily available should be attached to the SOP.

As with the technical SOPs, administrative SOPs can be written for a wide variety of activities (e.g., reviewing documentation such as contracts, test/QA plans and quality management plans; inspecting the work of others; determining organizational training needs; developing information on records maintenance; validating data packages; or describing office correspondence procedures). The administrative SOP needs to include a number of specific steps aimed at initiating the activity, coordinating the activity, and recording and/or reporting the results of the activity, tailored to that activity. For example, an assessment SOP should specify the authority for the assessment, technical criteria for assessments, what will be done with the results, and who is responsible for developing and implementing corrective action.

3.2 DESIGN OF VERIFICATION TESTS

Data collection operations will be performed during the verification tests in conformance with the test-specific test/QA plans. These operations must be designed so that one can determine whether the DQOs for the verification tests have been attained. Specific considerations regarding the design of data collection operations will be addressed in the test/QA plan for each verification test.

3.2.1 Intended Use of Data

The key use of information generated by verification tests is to prepare verification statements, which are independent and credible third-party assessments of the environmental performance characteristics of commercially-ready technologies through the evaluation of objective and quality assured data. These statements will include information such as pollutant emission removal efficiency rates and energy consumption rates as a function of operating conditions. The data thus generated may be used for a variety of purposes, including regulatory compliance decisions. For this reason, it is important that the data be reliable, defensible, and of known quality. Key acceptance criteria are described in the next section.

The program will not disseminate interim results from verification tests. As such, it will not be necessary to identify and state restrictions on the use of interim results.

3.2.2 Project Requirements for Data Quality Objectives

The program personnel, with input from the SG, will establish quantitative DQOs. These DQOs address the end use of the data and the data quality that is required for stakeholder decisions that are based on those data. Thus, the quantitative DQOs address the required quality of that final decision in terms of tolerable limits for the uncertainty of measurement data from the verification

tests. Examples of DQOs include the types of measurements to be made, the critical variables applicable to each technology, and the degree of uncertainty permissible in the verification statement.

During the development of a test/QA plan, the higher-level DQOs are broken down into component parts in order to derive quantitative DQI acceptance criteria (e.g., precision, accuracy, representativeness, completeness, and comparability) for each critical measurement. DQIs address the requirements that are placed on the nuts-and-bolts aspects of the sampling and measurement systems, which is why they are specified in the test/QA plan. Specific procedures for determining attainment of DQI acceptance criteria will be listed in the test/QA plan. The test/QA plan will be developed by the test leader with the assistance of the QM. It will be reviewed by the PM, the QM, and the EPA QM. Finally, it must be approved by the EPA PO before the verification test begins.

3.2.3 Performance Characteristics for Measurement Methods

Each test/QA plan is developed for a verification test of a particular technology. It will list all critical measurements to be made during that test, the procedures to be used for these measurements, and the performance characteristics of the measurement procedures. The program has extensive experience in developing and verifying new and/or nonstandard environmental measurement methods. Before any new and/or nonstandard measurement method is used in a verification test, its performance characteristics will be determined over the expected range of test conditions. If previous performance studies for this method are not available, they will be developed before the verification test and will be included as part of the test/QA plan. The types and frequencies of calibrations and the QC samples that are necessary to track a new method's performance will be determined during method validation and specified in the method's SOP.

3.2.4 Use of Accepted Analytical Procedures

Appropriate, approved procedures will be used for sampling and analysis and for method development and evaluation, when available. EPA-approved methods of sampling and analysis will be used whenever possible. The required quality and consistency of these methods and of new and/or nonstandard methods will be specified in the test/QA plan. These methods will be fully described in the test/QA plan and any SOPs that are needed. The program will also employ standard, recognized statistical and data assessment methods.

3.2.5 Instrument Calibration

Calibration of an analytical method establishes the quantitative relationship between the quantity of the analyte (e.g., in concentration units of parts per million) and the method's response (e.g., in volts). This relationship is used to convert subsequent method responses into the corresponding analyte quantity. Because the response of many methods has the tendency to drift with time, the calibration must be checked periodically to maintain a high degree of accuracy. Sampling and analytical equipment will be calibrated in accordance with the GVP, the test/QA plan, and any needed SOPs, and with the sampling or analytical method for which the equipment is used. The

frequency of calibration depends upon the type of equipment, the particular compound or element being measured, and the concentration level(s) of the compound or element. Analysts will evaluate instrument performance characteristics such as span drift, zero drift, noise, and linearity.

Analyses must fall within the calibrated range of the instrument. Samples will be screened so that calibration standards are appropriate for the anticipated measurement range of the samples. Calibration standards will be traceable to national standards, such as National Institute of Standards and Technology Standard Reference Materials (NIST SRMs) or NIST-traceable weights, when such standards are available. The stability of calibration standards will be monitored through the use of independently prepared samples that are analyzed with the calibration standards.

Calibration documentation will be maintained with each method in a central location and will be readily available for review by assessors and management. It will include such information as the instrument being calibrated, raw calibration data, calibration equations, analyzer identifications, calibration dates, certification periods, analyzer locations, calibration standards used and their traceabilities, identification of calibration equipment used, and personnel conducting the calibration.

3.2.6 Sample Collection, Selection, Preparation, and Site Selection

EPA sampling and site selection protocols, where available and appropriate, will be followed for all verification tests. Any needed sampling SOPs will be established before testing begins and will be attached to the test/QA plan.

Sample selection will be performed according to an approved experimental design that specifies the number and types of samples to be taken to achieve the DQOs and the specified DQI acceptance criteria described above. Where appropriate, statistical techniques will be used to develop the experimental design. All qualitative criteria for sampling representativeness must be met so that valid, unbiased test results are obtained. Proper sample collection and statistical sampling techniques will be used where necessary to avoid sampling bias.

3.2.7 Sample Handling, Tracking, Custody, Transportation, and Storage

To ensure that verification test samples and data are both secure and traceable, test leaders and the PM will develop written SOPs for sample handling, sample tracking, and chain of custody. These SOPs will be applicable to specific verification tests and will be documented in the test/QA plans for those tests. They will provide appropriate protection against inadvertent loss of samples or data, will ensure that verification test data generated are traceable, and will protect participants' proprietary information. A graded approach will be used in these procedures such that documentation and security levels are commensurate with the intended use of the verification test data and the degree of confidence needed in the quality of these data. A general discussion of sample handling and custody is given in *EPA Guidance for Quality Assurance Project Plans*. EPA QA/G-5 (EPA, 2002a).

The written sample custody procedures in the test/QA plans will include the following elements, as appropriate for the specific verification test:

- List the names and responsibilities of all sample custodians;
- Give a description and example of the sample numbering system;
- Define acceptable conditions (e.g., sample preservation, temperature, transit time, etc.) and plans for maintaining sample integrity;
- Give examples of sample log sheets, chain-of-custody forms, and sample labels that will be used to maintain sample custody and to document sample handling;
- Describe the method of sealing shipping containers with chain-of-custody seals to detect tampering;
- Describe procedures that will be used to maintain the chain of custody and to document sample handling;
- Provide for the archiving of all shipping documents and associated paperwork;
- Discuss procedures that will ensure sample security at all times;
- Describe procedures for within-laboratory chain-of-custody together with verification of the printed name, signature, and initials of persons who are responsible for custody of samples, extracts, or digests during analysis at the laboratory; and
- Describe procedures to document the disposal or consumption of samples.

Less detailed documentation of chain-of-custody procedures will be used when:

- Samples are generated and immediately tested within a facility or site; and
- Continuous, rather than discrete or integrated samples, that are subjected to real-time or near-real-time analysis (e.g., continuous monitoring).

A sample custodian will be designated for any verification test involving large numbers of samples. The sample custodian performs sample receiving inspection, physical acceptance of a group of samples intended for subsequent treatment or analysis, analysis tracking, and/or sample repository operation.

Necessary preservation techniques will be used for all perishable environmental samples as provided in the applicable methods. Perishable samples will be shipped in coolers with frozen ice-substitute gel packs when temperature control is necessary.

3.3 IMPLEMENTATION OF PLANNED OPERATIONS

The verification testing will proceed after the test/QA plan has been approved by the EPA PO. Verification tests will be conducted at RTI.

Verification tests will be performed in accordance with the test/QA plans. Test leaders will be responsible for implementing the test/QA plans and any needed SOPs and will periodically report on the progress of the verification tests to the PM. Their progress toward attaining the DQOs will be most directly monitored by the QM. The QM, under the direction of the PM, will

be responsible for technical assessments of verification tests. Such technical assessments may include TSAs and PEs at the test site during verification tests. The QM will conduct self-assessments of the quality and technical systems and ADQs after verification tests are completed.

Verification tests will be conducted according to the following requirements:

- All critical items and services used during the verification tests will conform to specifications given in the GVPs, test/QA plans, and any needed SOPs.
- All sampling, measurement, and analytical instrumentation and other measurement systems used for critical measurements during the verification tests will be checked to determine whether they comply with DQI acceptance criteria given in the test/QA plans.
- Whenever these measurement systems are found not to meet these DQI acceptance criteria, corrective actions will be taken before any further measurements are made to return the measurement systems' performance to acceptable levels.
- Measurement systems will be maintained and repaired in accordance with specifications given in the GVPs, test/QA plans, and any needed SOPs.
- All tools, gauges, and any other ancillary sampling, measuring, and testing equipment used for critical measurements during verification tests will be maintained and repaired in accordance with specifications given in the GVPs, test/QA plans, and any needed SOPs. Equipment found to be out of specification will not be used until it can be recalibrated or repaired and then demonstrated to be functioning within the specifications.
- All measurements and other verification activities will be documented in laboratory notebooks, laboratory data sheets, spreadsheets, computer files, and other appropriate storage media.
- Samples will be collected, handled, transported, and stored in accordance with specifications given in the GVPs, test/QA plans, and any needed SOPs. The chain-of-custody process will be maintained in accordance with specifications given in these documents.
- Verification test data will be transmitted, stored, validated, assessed, processed, and retrieved in accordance with specifications given in the GVPs, test/QA plans, and any needed SOPs.

3.4 ASSESSMENT AND RESPONSE

3.4.1 Frequency, Types and Reporting of Assessments

Sections A9.1 and B4.2 of EPA's *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a) specify that EPA will conduct one independent assessment of the quality system. Additional assessments of the quality system will be at a frequency determined by the EPA QM's professional judgment.

The QM will perform a self-assessment of the quality system on an annual basis in conjunction with the annual review and revision, as needed, of this document. This assessment frequency is

specified in *EPA Requirements for Quality Management Plans. EPA QA/R-2* (EPA, 2001a). A final report of the assessment findings will be prepared and will be presented to the EPA PO, the EPA QM, and the PM.

The QM will perform ADQs for a random selection of 10 percent of all the verification data for every verification test in accordance with Sections A9.1 and B4.2 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a). Final reports of the ADQs will be prepared and will be submitted with the verification report to the EPA PO, the EPA QM, the PM, and the QM.

RTI will follow the assessment schedule as specified in the EPA's *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a), Table 9.1 as much as possible, given funding constraints. TSAs and PEAs are required once per test. RTI interprets that to be once for each technology type testing, not for each individual product.

3.4.2 Assessments of Quality Systems

An assessment of a quality system is a qualitative evaluation of an organization's practices as they relate to its own quality system. The focus of the assessment process is on the organization's quality system rather than the technical systems or the quality of data and information that the organization produces to support a verification statement. Assessments are designed to evaluate the organization's quality system and to provide objective feedback about the quality system. An assessment seeks to determine if a quality system has been fully implemented and is operating in the manner prescribed by the organization's approved quality management plan. An assessment determines if an organization's quality management plan, quality management structure, policies, practices, and procedures are effective as implemented in assuring that environmental data have adequate quality for their intended purpose.

The criteria for assessments of the quality system will be this document. The assessments will be conducted according in accordance with EPA's *Guidance on Assessing Quality Systems. EPA QA/G-3* (EPA, 2003b).

The process of assessing a quality system has the following four stages:

1. **Planning the Assessment-** The scope of the assessment must be determined. The scope may be very broad because the interest may be in assessing how well the quality system is being applied in general. However, there may be specific questions that need to be addressed. Next, an assessment team will be identified. Team members should have sound interviewing skills, no conflicts of interest, competency in the technical fields being reviewed, and a thorough knowledge of quality management principles. During the planning stage, the team identifies the technical criteria (e.g., its quality management plan) and other background information for assessing the organization's quality system. The team will then determine what interviews and document reviews are necessary to properly assess the quality system. After the team has compiled and reviewed this information, it will develop a draft assessment plan, which the PM will review.

2. Conducting the Assessment- Upon arrival at the assessment site, the assessment team first will conduct an opening meeting with the organization's management and key personnel. Next, the team will interview management and key personnel as noted and scheduled in the assessment plan. The team also may review relevant files and consider case studies. The team will present its initial impressions of the information that it gathered during an exit meeting.
3. Evaluating the Results- The assessment team will assemble and review the information gathered during the assessment and will evaluate it based on the technical criteria documented in the assessment plan. The team then will formulate preliminary findings and recommendations in a written draft findings report.
4. Reporting the Findings and Recommendations- The draft findings report will be sent to the assessed organization for review. This step is important to ensure that there are no factual errors in the final report. The assessed organization's comments on the draft findings report will be reconciled by the assessment team. A final report of the assessment findings will be prepared by the lead assessor.

3.4.3 Technical Assessments

A technical assessment is a systematic and objective examination of a verification test during its implementation phase to determine whether environmental data collection activities comply with the test/QA, whether they are implemented effectively, and whether they are suitable to achieve DQOs that have been specified in the GVP and DQI acceptance criteria that have been specified in the test/QA plan.

A technical assessment is primarily a management tool and secondarily a technical tool. Technical assessments play an important role in documenting the implementation of the test/QA plan. They provide management with a tool to determine whether data collection activities are being implemented as planned. They provide management with both an increased understanding of the performance of critical measurements and a basis for improving such measurements. They also provide management with a tool to take action to correct any deviations that are discovered

Guidance for conducting technical assessments is given in EPA's *Guidance for Technical Audits and Related Assessments for Environmental Data Operations*, EPA QA/G-7 (EPA, 2000b).

Technical assessment tools include the following:

- TSAs qualitatively document the degree to which the procedures and processes specified in the approved test/QA plan are being implemented.
- PEs quantitatively document the ability of a measurement system to obtain acceptable results that are generated for a sample that originates outside of the verification test.
- Surveillance assessments are used to continuously or periodically assess the implementation of an activity or activities to determine conformance to established

procedures and protocols.

- ADQs examine verification test data (hardcopy and/or electronic) after they have been collected and verified by testing personnel.

3.4.4 Technical Systems Audits

Technical systems audits (TSAs) are thorough, systematic, qualitative, on-site assessments of the testing measurement systems used to collect data. They also determine that testing personnel and equipment are physically in place and functioning as stated in the planning documents. Assessors travel to the verification site, gather objective evidence, and produce a written findings report. Objective evidence is gathered by interviewing testing personnel, examining verification documents and records, and observing verification activities.

A TSA is often conducted shortly after a verification test starts to allow for early corrective action. For longer tests, TSAs are performed on a specified schedule throughout the life of the test. TSAs may be performed in conjunction with PE assessments. The schedule for TSAs can be found in EPA's *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a), Table 9.1.

Assessment checklists are prepared based on the test/QA plan and other planning documents, which are the technical criteria for the assessment. Any undocumented or unauthorized deviation from the test/QA plan will be noted during the TSA and will be included in the written assessment report.

The draft findings report will be sent to the assessed organization for review. This step is important to ensure that there are no factual errors in the final report. The assessed organization's comments on the draft findings report will be reconciled by the assessment team. A final report of the assessment findings will be prepared by the lead assessor.

3.4.5 Performance Evaluations

A performance evaluation (PE) is a quantitative assessment in which data are generated by a measurement system for a sample whose composition is known to the assessor. Although a PE can identify a problem quantitatively, it typically cannot determine the cause of the problem. To the extent possible, a PE sample will not be distinguishable in any way to the measurement system from actual samples. It will mimic actual samples in all possible aspects, except that its composition will be unknown to the analyst and known to the assessor. It will be treated routinely and not subjected to any special treatment. It will be used to determine if the measurement system's results are within the DQI acceptance criteria specified in the test/QA plan. PE results will be used to estimate the degree of bias in the measurement system.

A draft report of the PE findings will be sent to the assessed organization for review. This step is important to ensure that there are no factual errors in the final report. The assessed organization's comments on the draft report will be reconciled by the assessment team. A final report of the PE findings will be prepared by the lead assessor.

3.4.6 Surveillance Assessments

A surveillance assessment is the observation of ongoing work to document conformance with specified requirements and/or procedures, such as those given in a test/QA plan or SOP. A surveillance assessment is focused on a particular technical activity, rather than on the entire measurement system. It is typically less formal than other types of assessments, but it should also include appropriate preparation, conduct, reporting, and followup phases. As appropriate, a surveillance assessment may be employed as part of a TSA. As with other types of assessments, it is critical that the assessor be technically proficient in or knowledgeable about the activity being monitored.

The objective of a surveillance assessment is to provide confidence through real-time observations that an activity has been performed in accordance with approved and specified methods and procedures. It allows for immediate identification of any deficiency and initiation of action to correct the deficiency and its underlying cause. When deficiencies are identified, the PM should be notified promptly so that corrective action may be implemented. A surveillance assessment may allow for immediate notification of the status and performance of the laboratory to management if authorized by the scope of the assessment. It also can include followup to verify that corrective actions were implemented.

The draft findings of the surveillance assessment should be documented in writing and submitted immediately to the laboratory. The laboratory should provide a written response to the assessor that discusses the action taken to correct any observed deficiencies and to prevent similar deficiencies in the future.

3.4.7 Audits of Data Quality

An ADQ is an examination of data (hardcopy and/or electronic) after they have been collected and verified by testing personnel. It is conducted to determine how well the measurement system performed with respect to the DQOs and DQI acceptance criteria specified in the test/QA plan and whether the data were accumulated, transferred, reduced, calculated, summarized, and reported correctly. It documents and evaluates the methods by which decisions were made during treatment of the data. It documents the methods by which decisions were made during treatment of the data and evaluate those methods. It ensures that files are being maintained and secured, that chain-of-custody records are complete, and that raw data records are complete and in good order. Computer security will also be reviewed

Questions to be answered in an ADQ include:

- Is there sufficient documentation of all procedures used in the data collection effort to allow for repetition of the effort by a person or team with technical qualifications similar to those of the original data collector?
- Can the data be replicated by the original data collector?
- Is there sufficient documentation to verify that the data have been collected and reported according to these procedures?
- Is enough information provided to allow a potential user to determine the quality and limitations of the data and whether the intended use of the data is appropriate?
- Are the data of sufficient quality to attain DQOs, DQI acceptance criteria, and other measurement performance criteria?

ADQs entail tracing data through their processing steps and duplicating intermediate calculations. A representative set of the data is traced in detail from raw data and instrument readouts through data transcription or transference through data manipulation (either manually or electronically by commercial or customized software) through data reduction to summary data, data calculations, and final reported data. The focus is on identifying a clear, logical connection between the steps. Particular attention is paid to the use of QC data in evaluating and reporting the data set. For a large project, a statistical approach may be necessary to determine a representative number of data sets to be examined.

A typical ADQ will begin by reviewing available data from a verification test, by determining needed missing data, and by devising a plan for the assessment. The plan will usually include steps involving pursuing all available needed data, collecting it, and conducting an extensive review of the entire collection. Verification data will be statistically analyzed to determine whether they can be used to obtain a valid estimate of the DQIs. Statistical analyses of data will include, at a minimum, the average value of each parameter and its estimated uncertainty. When necessary, RTI statisticians can provide more advanced data evaluations.

The QM will prepare a report that details the results of chain-of-custody tracing, a study of data transfer, recalculations, a review of QA data, a study of project incidents that resulted in lost data, and a review of study statistics. The report states whether these measurements allow attainment of the DQOs and the DQI acceptance criteria specified in the test/QA plan. The ADQ report ends with conclusions about the quality of the data and their fitness for their intended use. The ADQ report is submitted with the verification report to the PM, the QM, the EPA PO, and the EPA QM for review.

3.4.8 Corrective Action

After an assessment, the PM or test leader is responsible for developing, implementing, and documenting corrective actions. It is critical that any necessary corrective action be timely and effective. In some situations, additional assessments may be needed to verify the effectiveness of the corrective actions. The PM or test leader will use a corrective action form to document any

deficiencies that require action and the resolution of them. This form will include the signatures of the individual identifying the need for corrective action and the individual responsible for implementing the corrective action. The problem requiring corrective action, the proposed corrective action, and the approach for evaluating the corrective action will be described.

The proposed corrective action should be reviewed by the lead assessor. This process helps ensure that the planned actions will be effective in resolving the problem areas and deficiencies reported by the assessment team.

The test leader will be responsible for the development of effective corrective actions of the problem areas or deficiencies discovered during the assessment. They will provide a written response to all assessment findings. Each finding will be addressed with specific corrective action steps and a schedule to implement them. Responses to adverse findings are required within 10 working days of receiving the assessment findings report in accordance with the requirements of Part B, Section 4.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a). The corrective action should address the following:

- Measures to correct each deficiency,
- Identification of all root causes of significant deficiencies,
- Determination of the existence of similar deficiencies,
- Corrective actions to preclude recurrence of similar deficiencies,
- Assignment of corrective action responsibility, and
- Completion dates for each corrective action.

The leader will implement corrective actions and provide requested evidence of correction. Once such evidence is received, the technical assessment will be closed unless a reassessment is planned.

3.5 ASSESSMENT AND VERIFICATION OF DATA USABILITY

Data verification will be performed by the testing staff in accordance with the quality requirements of the test/QA plans and any needed SOPs. As part of preparing a test/QA plan, RTI will develop methods to reconcile measurement data with DQOs. Usually, the test/QA plan will specify DQI acceptance criteria that allow testing personnel to determine during verification tests whether the DQOs will be attained at the end of the test.

Verification test results will be evaluated to determine the completeness, correctness, and conformance/compliance to these requirements. The goal of the data verification is to ensure and document that the results are what they purport to be, that is, that the reported results reflect what was actually done. When deficiencies in the results are identified, they will be documented for review by the PM, the QM, the EPA PO, and the EPA QM. Procedures for data verification are given in EPA's *Guidance on Environmental Data Verification and Data Validation*, EPA QA/G-8, (EPA, 2002c). All validated data arising from the verification tests will be disclosed in verification reports, even if the technology did not perform to the expectations of the technology provider.

QA/QC summaries will accompany regular progress reports for ongoing verification tests. QA summaries will include quantitative assessments of DQIs such as bias, precision, and completeness. Bias will be determined using personnel, equipment, and spiking material or reference material as independent as possible from those used in the calibration of the measurement system. Precision will be determined from replicate measurements of the same analyte. When possible and appropriate, the analyte will be divided and will be preserved separately to assess the variability of sample handling, preservation, and storage along with the variability of the analytical component of the measurement system. Completeness will be determined as the percentage of valid data out of the number of trials necessary to meet statistical design goals. Qualitative statements about sampling representativeness and comparability will be provided.

For verification reports and verification statements submitted to the PM, adequate QC data must be available in the submission to assess whether the DQOs and the DQI acceptance criteria were attained. After completion of a verification test, the QM will prepare the QA section of the verification report, which will describe both qualitatively and quantitatively the reliability and uncertainty inherent in the results. It will present the results of all QA activities, identify any quality problems encountered, and discuss the resolution of those problems through corrective action procedures. The QM and the EPA QM will review verification reports and verification statements to confirm that the verification test results are presented correctly

The QM will conduct an ADQ of a random selection of at least 10 percent of all verification data for each verification test in accordance with the requirements of Part B, Section 4.2 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a). The procedures for conducting an ADQ are described in Section 3.4 and in EPA's *Guidance for Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7* (EPA, 2000b). As part of the ADQ, the QM determines whether QC data attain DQI acceptance criteria and reconciles measurement data with DQOs. The ADQ report is submitted with the verification report for the PM, the QM, the EPA PO, and the EPA QM to review.

3.6 RECORD KEEPING AND DATA MANAGEMENT

GVPs will be retained by the program office for a period of not less than 7 years after the final payment of the contract in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a). Test/QA plans also will be retained by the program office for a period of not less than 7 years after the final payment of the contract. The PM is responsible for establishing procedures to securely store these documents.

Any SOPs, any raw data (electronic and printed) collected during verification tests, and any calculations or documents (including verification reports and verification statements) derived from such data will be retained by the program office for a period of not less than 7 years after the final payment of the contract in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a).

These data, calculations, and documents will be clearly identified by verification test, date, observer/author, and originating test laboratory. The test leader and/or the PM are responsible for establishing procedures to securely store these data, calculations, and documents.

Any project reviews and assessment reports that are generated by program will be retained by the program office for a period of not less than 7 years after the final payment of the contract in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan*. The test leader and/or the PM are responsible for establishing procedures to securely store these project reviews and assessment reports.

Verification reports and verification statements will be retained by the program office for a period of not less than 7 years after the final payment of the contract in accordance with the requirements of Part A, Section 5.3 of *Environmental Technology Verification Program Quality Management Plan* (EPA, 2003a). All validated data arising from the verification tests will be disclosed in verification reports, even if the technology did not perform to the expectations of the technology provider. The PM is responsible for establishing procedures to securely store these verification reports and verification statements.

4.0 REFERENCES

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